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10/556,652	11/16/2006	Klaus Forstner	HKH-23PCT	8501
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FRIEDRICH KUEFFNER 317 MADISON AVENUE, SUITE 910 NEW YORK, NY 10017			EXAMINER BERHANU, ETSUB D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/556,652	Applicant(s) FORSTNER, KLAUS	
	Examiner ETSUB D. BERHANU	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 1-19 are objected to because of the following informalities: claim 1 should be amended to replace the term "Noninvasive" in line 1 with the phrase - - A noninvasive - ; claims 2-12 should be amended to replace the term "Method" in line 1 with the phrase - - The method - -; claim 13 should be amended to replace the term "Device" in line 1 with the phrase - - The device - -; claims 14-19 should be amended to replace the term "Device" in line 1 with the phrase - - The device - -. Appropriate correction is required.
2. Claims 2-4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 2-4 recite method steps that are already disclosed in claim 1.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner what is intended to be claimed with the additional amendments made to claims 1 and 13. It seems as if claims 1 and 13 are directed towards a method and device for measuring blood components, as recited in lines 1-2 of the claims, but then the amendment to claims 1 and 13 recite the phrase "for determining a hemoglobin concentration as a blood component" and then even further recite that this determination is determined in addition to the concentration of a blood component. It is unclear

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if the hemoglobin concentration derived from the equation in claims 1 and 13 is the blood component or an additional blood component. Furthermore, the structure of the claims is lengthy and confusing. Also, it is unclear what is meant by the phrase "is considered" at the end of each claim. It is suggested that Applicant rewrite the claims to positively recite distinct method steps and distinct device components, each distinct step or component being on a new line of the claim. As best understood by the Examiner, the amendments to the claims require an arithmetic unit to be able to determine a hemoglobin concentration using the equation in claims 1 and 13.

5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 13 recite the broad recitation "blood component", and the claims also recite "hemoglobin" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-9, 11 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chance'417 (previously cited).

Figure 1 of Chance'417 discloses a device for measuring oxygen saturation, the device comprising: three light emitting diodes 22a,22b,22c emitting wavelengths of about 660nm, 805nm and 950nm; three photodiodes 24a,24b,24c; and an arithmetic unit capable of taking logarithms and performing divisions, multiplications, additions and subtractions (see description of Figure 1 and col. 7, line 10 – col. 8, line 15). The device is used to measure oxygen saturation, which is a measure of oxygenated hemoglobin in the blood divided by the total hemoglobin concentration of the blood, by successively generating wavelengths from each light emitting diode and conducting a measuring signal of the photodiodes to the arithmetic unit (see SUMMARY OF INVENTION). The arithmetic unit considers a quotient of logarithmized measured values when determining the oxygen saturation. The device is also used to measure myoglobin concentrations (col. 4, lines 47-49). As best understood, the equation in claims 1 and 13 is nothing more than an equivalent mathematical transformation (as discussed on pages 10-11 of the Applicant's Specification) of an already well known equation used in the art to determine hemoglobin concentrations (based on the Lambert-Beer Law). Chance'417 uses this law to determine hemoglobin concentrations. Therefore, it would have been within the skill of the art to use the equation of claims 1 and 13 with the invention of Chance'417 as it is merely a mathematical equivalent.

8. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Al-Ali et al.'065 (previously cited).

Al-Ali et al.'065 discloses a method for measuring arterial oxygen saturation (see ABSTRACT), the method comprising: generating light signals of a first wavelength at two successive times from a first light source, generating light signals of a second wavelength at two successive times from a second light source and generating light signals of a third wavelength at two successive times from a third light source,

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receiving the generated light at a photodiode once the generated light has been attenuated by human tissue, and conducting the measured signal from the photodiode to an evaluation unit, wherein the evaluation unit uses a quotient of logarithmized measured values to determine the arterial oxygen saturation measurement (see description of Figures 1A, 1B and col. 7, line 56 – col. 8, line 22). Arterial oxygen saturation is the percentage concentration of oxygenated hemoglobin divided by the total concentration of hemoglobin (col. 6, lines 63-66). As best understood, the equation in claims 1 and 13 is nothing more than an equivalent mathematical transformation (as discussed on pages 10-11 of the Applicant's Specification) of an already well known equation used in the art to determine hemoglobin concentrations (based on the Lambert-Beer Law). Al-Ali et al.'065 uses this law to determine hemoglobin concentrations. Therefore, it would have been within the skill of the art to use the equation of claims 1 and 13 with the invention of Al-Ali et al.'065 as it is merely a mathematical equivalent.

9. Claims 1, 6, 7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benaron'745 (previously cited).

Benaron'745 discloses a method for measuring a concentration of bilirubin (col. 1, lines 11-17), the method comprising: generating light signals of a first wavelength at two successive times from a first light source, generating light signals of a second wavelength at two successive times from a second light source, generating light signals of a third wavelength at two successive times from a third light source, receiving the generated light at a photodiode once the generated light has been attenuated by human tissue, and conducting the measured signal from the photodiode to an evaluation unit (see ABSTRACT and col. 3, line 50 - col. 5, line 26). As best understood, the equation in claims 1 and 13 is nothing more than an equivalent mathematical transformation (as discussed on pages 10-11 of the Applicant's Specification) of an already well known equation used in the art to determine hemoglobin concentrations (based on the Lambert-Beer Law). Benaron'745 uses this law to determine hemoglobin concentrations.

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Therefore, it would have been within the skill of the art to use the equation of claims 1 and 13 with the invention of Benaron'745 as it is merely a mathematical equivalent.

10. Claims 1-4, 6, 7, 9, 12, 13 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyagi et al.'125 (previously cited).

Figure 1 of Aoyagi et al.'125 discloses a device for measuring blood components (oxygen saturation, hemoglobin concentration, injected dyes), the device comprising: three light sources 1,2,3 emitting wavelengths of about 660nm, 805nm and 950nm; a photodiode 6; and an arithmetic unit 13 for taking logarithms and for performing divisions, multiplications, additions and subtractions (see BACKGROUND OF THE INVENTION and description of Figure 1). The device is used to determine the concentration of the blood components (col. 1, lines 8-12) by successively generating wavelengths from each light source and conducting a measuring signal of the photodiodes to the arithmetic unit. The arithmetic unit considers a quotient of logarithmized measured values when determining the blood component concentrations. As best understood, the equation in claims 1 and 13 is nothing more than an equivalent mathematical transformation (as discussed on pages 10-11 of the Applicant's Specification) of an already well known equation used in the art to determine hemoglobin concentrations (based on the Lambert-Beer Law). Aoyagi et al.'125 uses this law to determine hemoglobin concentrations. Therefore, it would have been within the skill of the art to use the equation of claims 1 and 13 with the invention of Aoyagi et al.'125 as it is merely a mathematical equivalent.

Response to Arguments

11. Applicant's arguments filed 10 July 2009 have been fully considered but they are not persuasive. Applicant fails to provide any arguments over the prior art other than "Turning now to the references, applicant submits that none of the references disclose a method or device for measuring blood components as recited in the amended claims now on file. Specifically, the references do not disclose the

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features presently added to the independent claims.” on page 10 of the Remarks. Merely stating that the prior art references do not disclose the features presently added to the independent claims, without specifically addressing the features of the current invention in relation to the cited prior art, is not persuasive. Furthermore, as discussed in paragraph 4 above, the amendments to the independent claims are unclear. As best understood, the amendments require an arithmetic unit to be able to determine a hemoglobin concentration using the equation in claims 1 and 13. The equation in claims 1 and 13 is nothing more than an equivalent mathematical transformation (as discussed on pages 10-11 of the Applicant’s Specification) of an already well known equation used in the art to determine hemoglobin concentrations (based on the Lambert-Beer Law). The prior art references each use this law to determine hemoglobin concentrations. For these reasons, the rejection of claims 1-19 is maintained.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

EDB